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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,049	03/28/2002	Jorg Rosenberg	0480/01221	5165

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,049	ROSENBERG ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, amendment and remarks filed 03/21/05. Claims 1 and 3-17 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 03/21/05 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the production of paroxetine hydrochloride and there is no antecedence for paroxetine hydrochloride in claim 4. Claim 1 is directed to paroxetine or one of its physiologically acceptable salts and further definition of what that physiologically acceptable salt should be was not stated before claim 5. A statement of what that physiologically acceptable salt is needs to be so recited or stated before the paroxetine hydrochloride is introduced.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 3 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by the 1998 PDR, pages 2851-2856.

The 1998 PDR in the relevant pages discloses a dosage form of paroxetine-HCl, the dosage form is a tablet and the each tablet contains paroxetine hydrochloride, dibasic calcium phosphate dehydrate, hydroxypropylmethylcellulose, polyethylene glycols, polysobate 80, sodium starch glycolate, titanium diode and one or more colors. The glass transition temperature recited for the polymer is a property of the polymer that cannot be separated from the polymer. It is noted that no specific polymer is recited and thus any synthetic polymer would meet those limitations

Therefore, the PDR reference meets the limitations of the claims.

6. Claims 1-3, 9, 10, 13-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Krape et al. (WO 99/00131, provided by applicants on Form PTO-1449).

Krape discloses solid dispersion of paroxetine in polyvinylpyrrolidone or polyethylene glycol polymeric carrier (abstract, page 5, lines 31-34). In a preferred embodiment, Krape discloses a process for forming the paroxetine-HCl polymer melt that involves heating a mixture of the paroxetine and polymer carrier to form a molten homogenous melt of paroxetine free base and the polymeric carrier and introducing dry hydrogen chloride into the vessel where a pharmaceutically acceptable paroxetine-HCl is formed in the molten state (page 6, line 27 to page 7 line 7). In example 1, Krape forms a homogenous melt of paroxetine free-base and PEG

in a flask and subsequently scraps the product from the flask to grind or mill into desired particle size. Granules of claim 16 read on particles.

The claimed invention is directed to a solid or semisolid preparation of paroxetine or one of its physiologically acceptable salt in the form of a molecular dispersion of paroxetine in a pharmaceutically acceptable polymer matrix having a glass transition temperature of >90 °C. The instant specification on page 1, lines 36-41, describes dispersions of two or more solids as solid solutions or molecular dispersions. The melt of paroxetine and polymer carrier in Krape is a solid solution or molecular dispersion of paroxetine in a polymer. No specific polymer is claimed in the instant invention. The glass transition temperature of a polymer is specific to a specific polymer. Thus the recited glass transition temperature of >90 °C is inherent to the polymeric carrier of the prior art. Paroxetine-HCl is formed when dry hydrochloric acid is introduced into the homogenous melt of the polymeric carrier and paroxetine free-base and this teaching meets the limitation of claim 2. In instant claim 3, 80% of the active ingredient is released after 30 minutes and this property is inherent to the paroxetine formulation of Krape. Regarding the limitation of substantially free of volatile organic solvent, it is noted that substantially free is not free of the organic solvents. A 4% volatile organic solvent detected in Example 5 of Krape would mean substantially free. There is no standard given or recited to define how much residual volatile organic solvent left in the product would constitute substantially free. Krape in page 13, lines 10 to 29 anticipates evaporating the solvent under vacuum, rotoevapoation, static vacuum drying and combinations and specifically states that the preparation is substantially free of solvents and in these lines defines what the prior art considers

to be substantially free of non-aqueous solvent. Thus, the teaching of Krape anticipates the claims.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krape et al. (WO 99/00131, provided by applicants on Form PTO-1449) in view of Remon et al. ("Extrusion-spheronisation: A literature Review," International Journal of Pharmaceutics, 116 (1995) pp 131-146).

The teaching of Krape is discussed above. Claim 6, which is dependent on claim 5, is taught in Krape because Krape employs paroxetine free-base in the formation of molten homogenous melt of paroxetine-HCl and polymer. Although Krape discloses forming a homogenous melt of paroxetine-HCl and polymeric carrier and optionally grinding or milling the melt to desirable particles (example 1 of Krape), Krape's melt was formed in a flask and not in an extruder. Thus regarding claim 4, Krape does not teach forming the melt in an extruder. However, it is known to form and shape melts in extruder. For example, in a review article by Remon et al., discloses that the most popular method of forming pellets from a melt is by extrusion (see page 132, left column and first full paragraph; and page 134, left column and first paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the paroxetine-HCl polymer melt according to Krape. One having ordinary skill in the art would have been motivated to perform the melt and shaping

process in an extruder according to what is known in the art with the expectation of producing directly tabletable particles or granules.

9. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krape et al. (WO 99/00131) in view of Miranda et al. (US 5,656,286).

Krape is described above. Krape discloses paroxetine-HCl PEG melt. Krape does not disclose forming the melt with copovidone polymer. However, Miranda discloses composition comprising paroxetine and copovidone, a copolymer vinyl acetate and vinylpyrrolidone (abstract; column 2, lines 51-57; column 6, lines 26-34; column 2, line 64 to column 3, line 1; column 3, lines 2-7; column 18, line 16; also see Buhler et al., US 6,592,900, column 1, lines 13 and 14 as a teaching reference for Vinylpyrrolidone/vinyl acetate copolymer as copovidone). Miranda is thus relied upon for a teaching of paroxetine and copovidone. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the paroxetine-HCl polymer melt according to Krape. One having ordinary skill in the art would have been motivated to substitute the polymer of Mirander for PEG with the expectation of forming a melt of the paroxetine.

Response to Arguments

10. Applicants' arguments filed 03/21/05 have been fully considered but they are not persuasive.

Applicants' claim is directed to a product that is substantially free of volatile organic solvent and the product of Krape is substantially free of the organic solvents (see page 13, lines 10 to 29 of Krape).

11. Applicants' arguments filed 03/21/05, with respect to Miranda and paroxetine vs. paroxetine-HCl have been fully considered and are persuasive. The rejection of claims 1 and 9-13 as anticipated by Miranda et al. (US 5,656,286) has been withdrawn.

12. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600